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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,059	03/02/2004	Sang Yup Lee	4240-103	3338

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INTELLECTUAL PROPERTY / TECHNOLOGY LAW
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EXAMINER	
ROOKE, AGNES BEATA	
ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 04/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/791,059	LEE ET AL.	
	Examiner	Art Unit	
	Agnes B Rooke	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-17 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-8 and 10-17 is/are rejected.

7)☒ Claim(s) 9 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 03/02/2004.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

Claims 1-17 are pending and currently under examination.

This application claims foreign priority from the Republic of Korea 10-2003-0062756 filed on 09/08/2003.

Objections to Specification

The priority application must be claimed in the first paragraph of the specification.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 16 and 17 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1, 2, 3, 5, 7, 8, and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 3, the names of IbpA, IbpB, IbpAB and HSP26 must be spelled out.

Claims 2, 5, 8, and 17 claim sHSPs by referring to the Table 1. These claims are improper because the specific protein claimed must be identified by a name or structure in the claim itself, otherwise the claim cannot be interpreted on its face. See PMEP 608.01(VI).

Claim 7 refers to a method that uses "*protein mixture*." It must be specified or defined what the protein mixture is, for example: combination of different proteins, or different proteins with other chemicals, or a single protein with other chemicals. Also, Claim 7 refers to "*increased number of spots*" on the gel. It is not clear what is the numerical value of the increase (for example, two-fold or 50%), thus values for the increase in number of spots on the gel should be provided.

In Claim 7 the name of the sHSPs must be spelled out.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 5, 7, 8, 10, 11, 16, 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Willsie et al., Small Heat Shock Protein p26 Associates With Nuclear Lamins and HSP70 in Nuclei and Nuclear Matrix Fractions From Stressed Cells, J. of Cellular Biochem., (2002), 84, p. 601-614.

Willsie et al. teaches α-crystalin protein p26 HSP bound to nuclear matrix proteins derived from embryos that were subject to 2-D gel electrophoresis, see page 606, right column and page 607, right column.

Therefore, Willsie et al. teach compositions of small heat shock proteins (Claim 1, 6), including α-crystalin protein p26 from Table 1 (Claims 2 and 5).

Willsie et al. teach a method of 2-D gel electrophoresis comprising adding small HSPs to a nuclear matrix protein mixture and subjecting the mixture to 2-D gel electrophoresis (Claim 7), wherein the sHSP is α-crystalin p26 from Table 1 (Claim 8). Claims 10 and 11 are included in this rejection because sHSPs were effective.

Willsie et al. teach method of using sHSPs as inhibitors of protein degradation because in control blots the proteins were degraded (Claims 16 and 17). See Figure 2, page 606, and Figure 3, page 607.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Kitagawa et al., Escherichia coli Small Heat Shock Proteins, IbpA and IbpB, Protect Enzymes from Inactivation by Heat and Oxidants, Eur. J. Biochem., (2002), 269, p. 2907-2917.

Kitagawa et al. teach two small heat shock proteins of E. coli, IbpA and IbpB. See page 2909, right paragraph (*Expression and purification of His-IbpA and His-IbpB* section).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lubman et al. (U.S. 2002/0098595 A1).

Lubman et al. teach that heat shock proteins have been identified from the 2-D gel, See [0137] page15; and provide a method analogous to the 2-D gel, where the method can be used for proteome analysis. See [0151] page 17.

Therefore, it would have been obvious to a person skilled in the art to design a method for the analysis of proteomes using 2-D gel electrophoresis where the method is analogous to the 2-D gel and uses heat shock proteins as disclosed by Lubman et al.

Claims 7, and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Willsie et al. in view of Kitagawa et al., Escherichia coli Small Heat Shock Proteins,

IbpA and IbpB, Protect Enzymes From Inactivation by Heat and Oxidants, Eur. J. Biochem., (2002), 269, p. 2907-2917.

The teachings of Willsie et al. are discussed above. Willsie at al does not teach the method for the gel electrophoresis wherein the protein mixture is total protein is specific cells of prokaryotes and eukaryotes, such as E.coli and Pseudomonas.

The teachings of Kitagawa et al. are disclosed above. Kitagawa et al. teach two small heat shock proteins of E. coli, IbpA and IbpB, but do not teach 2-D gel electrophoresis.

It would have been obvious to a person skilled in the art to design a method for the 2-D gel electrophoresis as disclosed by Willsie et al. and use a protein mixture of IbpA or IbpB (sHSPs) from E.coli as disclosed by Kitagawa et. el. because small heat shock proteins help to stabilize other proteins and remain associated with unfolded proteins in 2-D gel electrophoresis.

Prior art of record

1. Studer et al., Chaperone Activity and Homo- and hetero-oligomer Formation of bacterial Small Heat Shock Proteins, J. of Biol. Chemistry, (2000), 275, p. 37212-37218, is relevant to Claim 1 and 4 where several bacterial heat shock proteins were purified and their chaperone activity demonstrated. See page 37213.

2. Ehrnsperger et al., Stabilization of Proteins and Peptides in Diagnostic Immunological Assays by the Molecular Chaperone Hsp25, Analyt. Chem., (1998), 259,

p. 218-225, is relevant to Claims 1, 2, 4, 5, where the stabilization of proteins by Hsp25 is disclosed.

3. Garrett et al., A small Heat Shock Protein Stably Binds Heat-denatured Model Substrates and Can Maintain a Substrate in a Folding–competent State, EMBO J., (1997), 16(3), p. 659-671 is relevant to Claims 1, 2, 4, 5 where the sHSP disclose chaperone activity. See page669.

4. Han et al., Proteome Analysis of Metabolically Engineered Escherichia coli Producing Poly(3-Hydroxybutyrate), J. of Bacteriology, (2001), p. 301-308 is relevant to Claims 1 and 15 where the small heat shock proteins were used in 2-D gel, and proteome expression was observed when proteins were placed onto 2-D gels and separated. See page 302, right paragraph.

Conclusion

No Claims are allowed.

Claim 9 is objected to because it depends from rejected independent claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

AR

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER